

EXHIBIT P

LAW OFFICES
WAGSTAFF & CARTMELL LLP

THOMAS W. WAGSTAFF
THOMAS P. CARTMELL
MARC K. ERICKSON
JONATHAN P. KIEFFER
THOMAS L. WAGSTAFF**
ERIC D. BARTON†††
BRIAN J. MADDEN
JEFFREY M. KUNTZ
THOMAS J. PREUSS
THOMAS A. ROTTINGHAUS

4740 GRAND AVENUE – SUITE 300
KANSAS CITY, MISSOURI 64112

(816) 701-1100
FAX (816) 531-2372

TYLER W. HUDSON****†
DIANE K. WATKINS***
BRANDON D. HENRY
SARAH B. RUANE
CHRISTOPHER L. SCHNIEDERS††
VANESSA H. GROSS
ADAM S. DAVIS
JACK T. HYDE Δ
DAVID M. MCMASTER*
JOAN D. TOOMEY
ANDREW N. FAES Δ
ASHLEY D. DOPITA*

ADMITTED IN MISSOURI AND KANSAS
Δ ADMITTED IN MISSOURI
*ADMITTED IN KANSAS

JOHN P. O'CONNOR Δ †
P.J. O'CONNOR Δ †
DANIEL LOBDELL Δ †

**ADMITTED IN MISSOURI, KANSAS AND ARKANSAS
***ADMITTED IN MISSOURI, KANSAS AND COLORADO
††ADMITTED IN MISSOURI, KANSAS AND ILLINOIS
****ADMITTED IN MISSOURI, KANSAS AND
DISTRICT OF COLUMBIA
†††ADMITTED IN MISSOURI, KANSAS AND UTAH
†OF COUNSEL

SCOTT M. CROCKETT††
PHILLIP P. ASHLEY*†
DARYL J. DOUGLAS Δ †

May 23, 2013

Via e-mail and U.S. Mail

Benjamin Watson
Christy Jones
Donna Jacobs
Butler Snow
PO Box 6010
Ridgeland, MS 39158

RE: TVM Litigation – Production of 510(k)'s
Our file: 430-2000

Dear Mr. Watson:

I am writing to address the continuing difficulties we are having regarding production of documents, specifically the complete and final versions of the 510(k)'s for the TVT "classic", the TVT-Blue, TVT-S, TVT-O, and TVT-Abbrevio.

The third day of the regulatory 30(b)(6) examination where Ms. Susan Lin was your corporate designee occurred on May 2. At our request, Ms. Lin brought copies of the 510(k) submissions for the 6 TVT products. At the conclusion of the examination on May 2, we were given an opportunity to examine these materials. These documents, which were apparently stored in a Central Regulatory Affairs fileroom right down the hall from where Ms. Lin works, are different from the previous versions of the 510(k)'s we have received. Most notably, the 510(k) for the TVT "classic" contains an additional 17 pages which are substantive in nature, describing changes to the IFU requested by the FDA as a condition of clearance on this device. The 510(k) for the TVT-Abbrevio is nearly triple the length of the 510(k) that was previously provided to us and designated as the "Regulatory Affairs Central File"

Benjamin Watson
Christy Jones
Donna Jacobs
May 23, 2013
Page 2

version, mostly because it contains multiple appendices that were not in the version you had previously represented to us as final. While someone from Ms. Kabbash's office was kind enough to make copies of these documents on the evening of May 2, I still do not believe we have been provided produced, bates-stamped copies in ESI-compliant format as of the date of this letter.

In addition the substantive differences in the TVT "classic" and the TVT Abbrevio 510(k) described above, The 510(k)'s for the TVT Blue, TVT-O, TVT-S, and TVT-exact contained multiple color pages which have previously been produced to us only in black and white. Again, while someone from Ms. Kabbash's office was kind enough to make copies of these documents on the evening of May 2, I still do not believe we have been provided produced, color, bates-stamped copies in ESI-compliant format as of the date of this letter. In addition, most of these 510(k)'s, including the TVT "classic" and Abbrevio, contained CD-ROMs contained in a pocket just inside the front cover. We did not have the time or the resources to examine the contents of these CD's to verify that there was nothing on them that was not contained within the paper documents. In the case of the TVT "classic" that particular submission contained a micro-floppy disc inside the binder. Even if we had had the time to examine it, we did not have the specialized equipment with us to read data stored in that archaic format. I still do not believe we have been provided with produced, color, bates-stamped copies in ESI-compliant format as of the date of this letter.

With depositions regarding the TVT products continuing on an ongoing basis, it is imperative that we get bates stamped versions of these documents produced in ESI compliant format as soon as possible. Additionally, we would like to request that a complete collection of the regulatory fileroom where these documents are stored be undertaken as soon as possible, and that you provide a summary by bates range of any materials produced from this fileroom including the aforementioned CD-ROM discs and microfloppy discs, as well as any other portable or storage media contained within this fileroom. Please let me know as soon as possible when this can be completed.

Very truly yours,

/s/ Andrew N. Faes

Andrew N. Faes

ANF/bh

cc: Phil Combs
David Thomas
Bryan Aylstock
Renee Baggett